PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>BRAND NAME (generic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMLA (lidocaine 2.5% and prilocaine 2.5% cream)</td>
</tr>
<tr>
<td>(lidocaine hcl 2% gel)</td>
</tr>
<tr>
<td>(lidocaine hcl 4% gel)</td>
</tr>
<tr>
<td>(lidocaine 5% ointment)</td>
</tr>
<tr>
<td>(lidocaine hcl 4% solution)</td>
</tr>
<tr>
<td>PLIAGLIS (lidocaine and tetracaine 7-7% cream)</td>
</tr>
<tr>
<td>SYNERA (lidocaine and tetracaine 70-70mg patch)</td>
</tr>
</tbody>
</table>

Status: CVS Caremark Criteria
Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

EMLA
EMLA cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on:
- normal intact skin for local analgesia.
- genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.

EMLA cream is not recommended in any clinical situation when penetration or migration beyond the tympanic membrane into the middle ear is possible because of the ototoxic effects observed in animal studies.

Lidocaine 2% gel
Lidocaine hcl 2% gel is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Lidocaine 4% Gel
Lidocaine hcl 4% gel is indicated for the following:
- Stage I - IV pressure ulcers
- Venous stasis ulcers
- Ulcerations caused by mixed vascular etiologies
- Diabetic skin ulcers
- First and second degree burns
- Post-surgical incisions, cuts and abrasions

Lidocaine 5% Ointment
Lidocaine 5% ointment is indicated for production of anesthesia of accessible mucous membranes of the oropharynx. It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.
**Lidocaine 4% Solution**
Lidocaine hcl 4% topical solution is indicated for the production of topical anesthesia of accessible mucous membranes or the oral and nasal cavities and proximal portions of the digestive tract.

**Pliaglis**
Pliaglis cream is a combination of lidocaine, an amide local anesthetic, and tetracaine, an ester local anesthetic, and is indicated for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.

**Synera**
Synera is a combination amide and ester local anesthetic indicated for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodessication and shave biopsy of skin lesions.

**COVERAGE CRITERIA**
The requested drug will be covered with prior authorization when the following criteria are met:

- **Lidocaine 5% ointment** is being prescribed for any of the following:
  - Production of anesthesia of accessible mucous membranes of the oropharynx
  - As an anesthetic lubricant for intubation
  - For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites

  OR

- **Lidocaine-prilocaine 2.5%-2.5% cream (Emla)** is being prescribed as a topical anesthetic for use on either
  - Normal intact skin for local analgesia
  - Genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia

  OR

- **Lidocaine hcl 2% gel** is being prescribed for any of the following:
  - Prevention and control of pain in procedures involving the urethra
  - Topical treatment of painful urethritis
  - As an anesthetic lubricant for endotracheal intubation (oral and nasal)

  OR

- **Lidocaine hcl 4% gel** is being prescribed for any of the following:
  - Stage I - IV pressure ulcers
  - Venous stasis ulcers
  - Ulcerations caused by mixed vascular etiologies
  - Diabetic skin ulcers
  - First and second degree burns
  - Post-surgical incisions, cuts and abrasions

  OR

- **Lidocaine hcl 4% topical solution** is being prescribed for the production of topical anesthesia of accessible mucous membranes or the oral and nasal cavities and proximal portions of the digestive tract

  OR

- **Lidocaine-tetracaine 7%-7% cream (Pliaglis)** is being prescribed for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal

  OR

- **Lidocaine-tetracaine 70-70mg patch (Synera)** is being prescribed for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodessication and shave biopsy of skin lesions

**AND**
The requested drug will not be used as part of a compounded product.

Quantity Limits apply.
**POST LIMIT QUANTITY**

This quantity limit should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantities to approve per 25 days*</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMLA 2.5%-2.5% cream lidocaine-prilocaine 2.5-2.5% cream</td>
<td>60 gm</td>
</tr>
<tr>
<td>Lidocaine 2% gel</td>
<td>60 gm</td>
</tr>
<tr>
<td>Lidocaine 4% gel</td>
<td>60 gm</td>
</tr>
<tr>
<td>Lidocaine 5% ointment</td>
<td>100 gm</td>
</tr>
<tr>
<td>Lidocaine 4% solution</td>
<td>100 mL</td>
</tr>
<tr>
<td>Pliaglis 7-7% cream</td>
<td>60 gm</td>
</tr>
<tr>
<td>Lidocaine-tetracaine 7-7% cream</td>
<td>60 gm</td>
</tr>
<tr>
<td>Synera 70-70mg patch</td>
<td>4 patches</td>
</tr>
<tr>
<td>Lidocaine-tetracaine 70-70mg patch</td>
<td>4 patches</td>
</tr>
</tbody>
</table>

*The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

*These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit.

**REFERENCES**

3. LDO Plus (Lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.